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ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR 09/755,269 01/05/01 ANTIGNANI Α P-3734C1C1 **EXAMINER** 026253 HM12/0712 GITOMER, R BECTON, DICKINSON AND COMPANY ART UNIT PAPER NUMBER 1 BECTON DRIVE FRANKLIN LAKES NJ 07417-1880 1623 DATE MAILED: 07/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

policant(s)

Office Action Summary

Application No. 09/755,269

Applicant(s)

Antignani et al.

Examiner

Ralph Gitomer

Art Unit **1623**

The MAILING DATE of this communication appears on the cover sheet with the correspondence address	
Period for Reply	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET THE MAILING DATE OF THIS COMMUNICATION.	
communication Failure to reply within the set or extended period for reply will, b	cation.
Status	
1) \square Responsive to communication(s) filed on <u>Jan 5, 20</u>	001
2a) ☐ This action is FINAL . 2b) ☑ This ac	tion is non-final.
3) Since this application is in condition for allowance closed in accordance with the practice under Ex pa	except for formal matters, prosecution as to the merits is arte Quayle, 1935 C.D. 11; 453 O.G. 213.
Disposition of Claims	
4) 💢 Claim(s) <u>1-23</u>	is/are pending in the application.
4a) Of the above, claim(s)	is/are withdrawn from consideration.
5) Claim(s)	is/are allowed.
6) Claim(s)	is/are rejected.
7) Claim(s)	is/are objected to.
8) 💢 Claims <u>1-23</u>	are subject to restriction and/or election requirement.
Application Papers	
9) The specification is objected to by the Examiner.	
10) The drawing(s) filed on is/ard	e objected to by the Examiner.
11) The proposed drawing correction filed on	is: a)□ approved b)□ disapproved.
12) The oath or declaration is objected to by the Exam	niner.
Priority under 35 U.S.C. § 119	
13) Acknowledgement is made of a claim for foreign p	priority under 35 U.S.C. § 119(a)-(d).
a) ☐ All b) ☐ Some* c) ☐ None of:	
1. Certified copies of the priority documents have been received.	
2. Certified copies of the priority documents have been received in Application No	
3. Copies of the certified copies of the priority of application from the International Bure *See the attached detailed Office action for a list of the second seco	
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s)	
15) Notice of References Cited (PTO-892)	18} Interview Summary (PTO-413) Paper No(s).
16) Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) Notice of Informal Patent Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	20) Other:

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Please inform the examiner of any related cases to this case, pending, allowed or abandoned.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to a composition of heparinase, classified in class 435, subclass 13.
- II. Claim 19, drawn to a method for eliminating the effects of heparin, classified in class 435, subclass 2.
- III. Claim 20, drawn to a method for preparing a composition of heparinase, classified in class 435, subclass 13.
- IV. Claims 21-22, drawn to a tube for preparing heparin, unclassifiable.
- V. Claim 23, drawn to a method for making a tube, unclassifiable.

The inventions are distinct, each from the other because:
Inventions I and II are related as product and process of
use. The inventions can be shown to be distinct if either or
both of the following can be shown: (1) the process for using the
product as claimed can be practiced with another materially
different product or (2) the product as claimed can be used in a
materially different process of using that product (MPEP
§ 806.05(h)). In the instant case the method could be practiced
with other compositions.

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Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of making could be used to make other compositions.

Inventions I and IV are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the apparatus could be used for other compositions.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because Group V is directed to making an apparatus and Group I is directed to a composition.

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Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the method of making of Group III could be used to make other compositions for other methods.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the methods are entirely unrelated.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the use of a composition and a method of making an apparatus are entirely unrelated.

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Inventions III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus could be used to prepare other compositions.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the method for making a composition is entirely unrelated to a method for making an apparatus.

Inventions IV and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention V has separate utility such as making other types of apparatus for other functions. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on (703) 308-1701. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234. For 24 hour access to patent

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application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button **Patent Electronic Business Center** for more information.

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R. Cectories

Ralph Gitomer Primary Examiner Group 1623

> RALPH GITOMER PRIMARY EXAMINER GROUP 1200